Can the recent public notice by the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy be helpful in combating the irrational use of herbal drugs?

Dear Editor,

Recently, on January 15, 2016, the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), Government of India, released a public notice (K.11025/01/2015-DCC9AYUSH0-Part) for the consumers and the stakeholders of Ayurveda, Siddha, and Unani (ASU) drugs for promoting the safe use of these drugs. It states that these drugs are regulated under the Drugs and Cosmetics Act, 1940, and rules there under. Furthermore, it states that these drugs containing potential hazardous constituents of plants, animals, and mineral origin as specified in the schedule E (1), rule 161 (2), of the Drugs and Cosmetics Rule, 1945, are needed to be taken under expert medical supervision. For the manufacturers of ASU drugs, the notice states that they should imprint, "Caution: To be taken under medical supervision" both in English and Hindi on the labels of such ASU drugs, which contain potentially hazardous ingredients of plants, animal, or mineral origin, as specified in the schedule E (1), rule 161 (2), of the Drugs and Cosmetics Rule, 1945. The notice also states that contravention of this provision may be brought to the notice of appropriate licensing authority for appropriate action.[1]

The public notice primarily focuses on public for creating awareness and manufacturers for putting a label of caution on the drugs. The contravention of which, in the part of a manufacturer, is liable for appropriate action. However, the notice forgot to mention about the most important intermediary between the consumers and the manufacturer, "the retailer"- the retail chemists and druggists actually selling the medicines with or without medical prescription. This is very much pertinent in Indian scenario as over-the-counter selling of medicines without prescription is very rampant. One of the studies eliciting the characteristics of pharmacies in Central India revealed that 60.6% (n = 475) of pharmacies dispense ASU drugs and 40% (n = 475) dispense medicines without prescription.[2]

Given these facts, a mention of pharmacies in the notice is expected. The pharmacies should have been given the option of dispensing ASU medicines with caution and with the prescription of qualified ASU physicians only. Moreover, dispensing of medicines without medical prescription leads to the irrational use of these drugs.

Hence, the notice may be partially helpful in alleviating the problem of the irrational use of herbal drugs in India. In one way, it focuses on public who are cautioned about buying medicines through online shopping without any medical prescription as these may contain potentially hazardous plant, animal, or mineral ingredients, and on the other hand, it cautions the manufacturers for labeling these drugs with caution. However, the fact is the irrational use of herbal drugs is widespread in India. As per the estimations of the World Health Organization, up to 80% of the populations in some Asian and African countries still depend on herbal medicines.[3] Here, one thing is clearly evident that when there is such a huge usage of herbal drugs, the possibility of irrational use cannot be denied.

One of the studies on presurgical patients revealed that 22% of the preoperative patients use one or the other types of herbal medicine.[4] About four decades ago, an outbreak of a veno-occlusive disease with 42% mortality occurred in Central India following the consumption of cereals mixed with seeds of a plant (*Crotalaria* sp.) revealed the presence of pyrrolizidine alkaloid.[5] A study revealed that most of the ayurvedic preparations may culminate in lead poisoning as evidenced by hematological parameters such as higher blood lead, more basophilic stippling, lower hemoglobin, and higher protoporphyrin in patients consuming standard ayurvedic medicines.[6]

Several biological repercussions have been noticed owing to the irrational use of herbal drugs. Let us take a few such examples which have biological consequences such as *Vaccinium uliginosum* and *Vaccinium oxycoccos* (cranberry) cause an increased risk of bleeding. *Aristolochia* species is known to cause acute renal failure, while aconite roots may cause aconitine poisoning (local anesthetic effects, diarrhea, convulsions, arrhythmias, or death). St John's wort and *Camellia sinensis* (green tea) may antagonize warfarin, thus increasing the risk for thrombotic complications. Blue (*Caulophyllum thalictroides*) and black cohosh (*Actaea racemosa* and *Cimicifuga racemosa*) may be hepatotoxic. *Datura* species may result in anticholinergic poisoning and "yulan" (*Stephania sinica*) may cause tetrahydropalmatine poisoning (depressant action on cardiorespiratory and nervous systems).[7,8]

The majority of ayurvedic formulations available in the market are either spurious or adulterated or misbranded.[9] Most commercially available preparations do not even confirm to the delineations of the ancient ayurvedic texts. The herbs lose their

medicinal properties a year after collection, powders made from them remain effective for 6 months only, and the paste remain effective for 1 year. Despite all these facts, the formulations do not usually carry an expiry date or potential side effects.[10]

Steps such as health education and awareness, legislation to ban street drug vendors, and standardization of drug manufacturing units can be implemented to control the above-mentioned problems.[11] Many of the pharmacies in AYUSH system are not good manufacturing practices (GMP)-certified, and a few are not even licensed. As per the reports of the Ministry of AYUSH, 17% of AYUSH pharmacies are not GMP-certified, of which 58.20% are of Ayurveda, 18.10% are of Unani, 17.90% are of Siddha, and 5.80% of pharmacies are of homeopathy origin.[12] These facts indicate that necessary steps need to be taken to bring rationality in drug manufacturing and the usage at consumer level.

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Conflicts of interest

There are no conflicts of interest.

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